


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Weiner and Hartmann
Application No. : 09/888,326
Conf. No. : 7237
Filed : June 22, 2001
For : METHODS FOR ENHANCING ANTIBODY-INDUCED CELL LYSIS
AND TREATING CANCER

Examiner : J. Eric Angell
Art Unit : 1635

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 9 September, 2004.


Alan W. Steele, Reg. No. 45,128

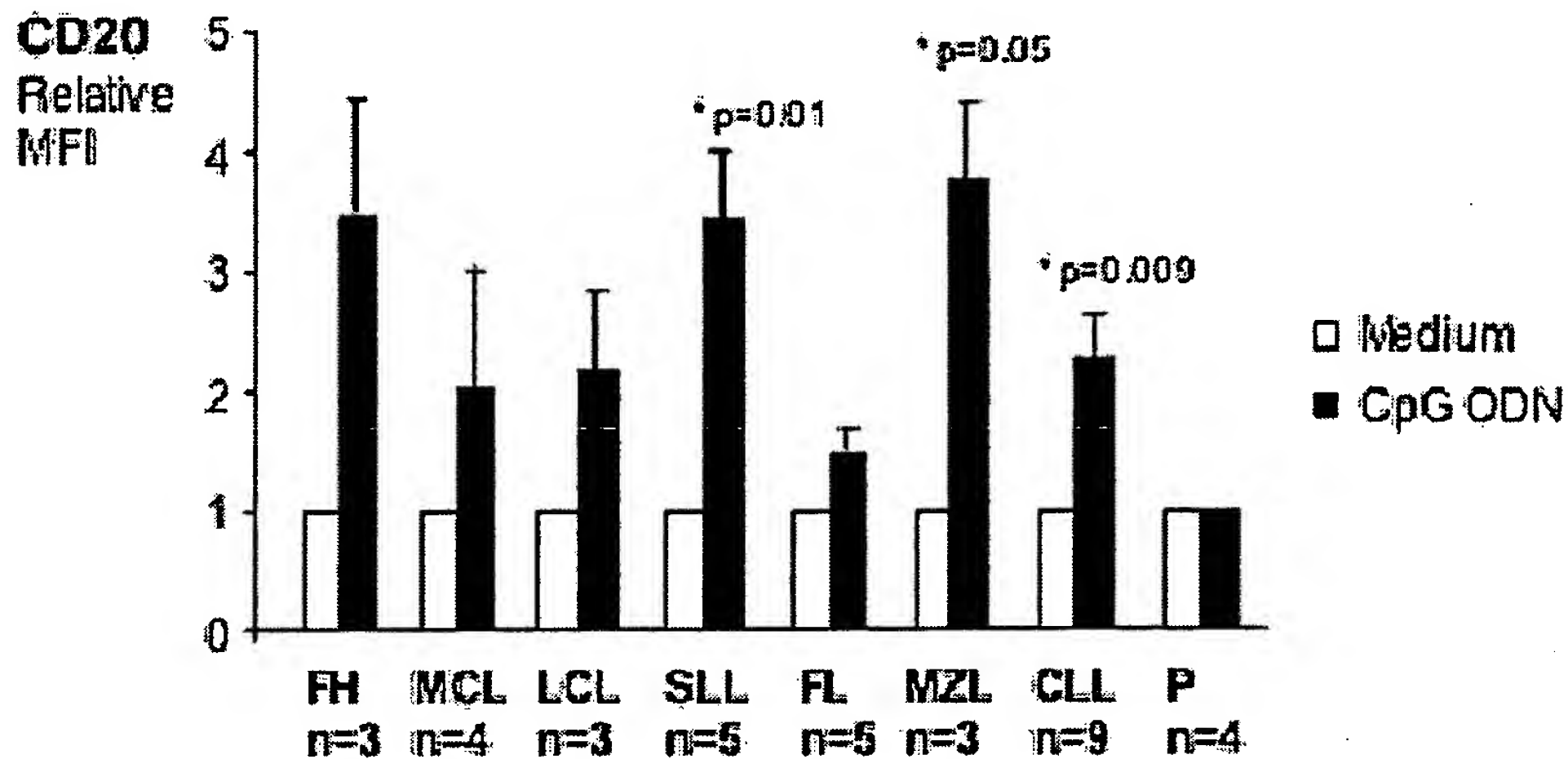
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132 OF GEORGE J. WEINER

1. I, George J. Weiner, am an inventor of the subject matter of the above-identified patent application. I make this declaration in support of this application.
2. I am aware of the rejection by the Examiner of claims 1, 2, 5, 7-15, 17-21, 24, 34, and 43 under 35 U.S.C. 112, first paragraph, in the non-final Office Action mailed April 20, 2004, in the above-identified patent application, in which the Examiner asserted that the specification is not enabling for claims drawn to upregulating the expression of CD20, CD19, or CD22 in any cell other than a B-CLL or marginal zone lymphoma cell.
3. I hereby declare that data recently obtained by me and my co-inventor indicates that most B-cell malignancies, other than plasmacytomas, respond to CpG oligonucleotides (CpG ODN) by increasing expression of CD20. In particular, analysis of 41 individual patient-derived tumor samples revealed that B-cell chronic lymphocytic leukemia, small lymphocytic lymphoma, and marginal zone lymphoma were highly sensitive to CpG ODN, and follicular lymphoma, mantle

cell lymphoma, and large cell lymphoma showed somewhat less but nevertheless substantial sensitivity to CpG ODN. This data is presented in following figure.



CpG ODN-induced upregulation of CD20 on different types of primary malignant B cells.

Different types of primary malignant B cells and B cells derived from follicular hyperplasia were incubated with medium alone (open bars) or with CpG ODN 2006 (5 µg/ml; black bars). After 48 hours, CD20 expression was determined by flow cytometry. Bars represent the means (\pm SEM; n: number of samples) of the MFI of different surface molecules relative to the baseline expression on day 0 (set as 1). * for $p < 0.05$. FH follicular hyperplasia; CLL chronic lymphocytic leukemia; SLL small lymphocytic lymphoma; FL follicular lymphoma; MZL marginal zone lymphoma; LCL large cell lymphoma; MCL mantle cell lymphoma; P plasmacytoma.

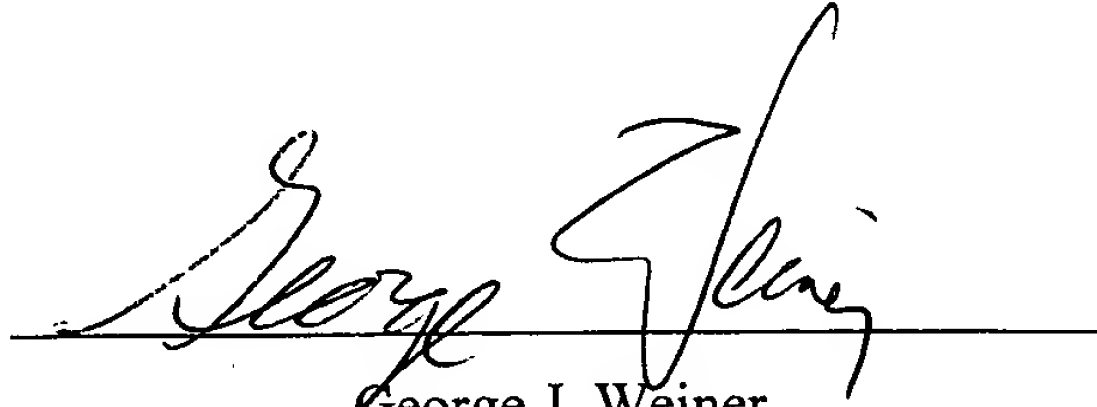
4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

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punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7/27/04


George J. Weiner